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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:			
Applicant:	**DeVico, et al..**	**Docket No.:**	**4115-144**
Application No.:	**09/684,026**	**Examiner:**	**U. Winkler**
Filed:	**October 6, 2000**	**Art Unit:**	**1648**
Title:	**VIRUS COAT PROTEIN/RECEPTOR CHIMERAS AND METHODS OF USE**		

EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, Washington, D.C., 20231 and Express Mailed under the provisions of 37 CFR 1.10.

Blake Crouch

March 12, 2002
Date

EV037733021US
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RESPONSE TO FEBRUARY 12, 2002 OFFICE ACTION IN U. S. PATENT APPLICATION NO. 09/684,026

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action dated February 12, 2002 in the above-identified U.S. Patent application, wherein a restriction requirement was imposed against the following claim groups:

Group 1 (claims 1-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Retroviridae (HIV, SIV, FIV, FeLV), classified in class 424, subclass 207.1;

Group 2 (claims 1-5, 10-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Parvoviridae (FPV = feline panleukemia virus), classified in class 424, subclass 233.1;

Group 3 (claims 1-5, 10-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Herpesviridae, classified in class 424, subclass 229.1;

Group 4 (claims 18-23) drawn to a chimeric polypeptide which contains a third heterologous domain, classified in class 424, subclass 193.1;

Group 5 (claims 25-28) drawn to a polynucleotide encoding a chimeric polypeptide, classified in class 536, subclass 23.4;

Group 6 (claims 29-33) drawn to an antibody to the chimeric polypeptide, classified in class 530, subclass 388.3;

Group 7 (claims 34-43 and 45) drawn to a method of administering an effective amount of a chimeric polypeptide to achieve antibody production, classified in class 800, subclass 3;

Group 8 (claims 34-43 and 45) drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve antibody protection, classified in class 800, subclass 3;

Group 9 (claims 38 and 44) drawn to a method of administering an effective amount of a chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3;

Group 10 (claims 38 and 44) drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3;

Group 11 (claims 46-65) drawn to a method of identifying an agent that inhibits an interaction between the virus and a co-receptor of the virus and a receptor, classified in class 436, subclass 501; and

Group 12 (claims 66-72) drawn to a method of identifying an agent that inhibits viral infection of a cell, classified in class 435, subclass 7.1;

applicants hereby elect, with traverse, Group 1 including claims 1-17 and 24.

Applicants' reasons for the traversal of the restriction requirement are set out below, and on such basis, applicants request the Office to reconsider the restriction of the pending claims, and to

withdraw same in favor of consolidated examination and prosecution of pending claims in the application.

The Office concludes that the inventions of Group 1 and 4 are distinct because they have acquired a separate status in the art as shown by their different classification and divergent subject matter. Applicants disagree because there is no evidence that the two groups of claims have attained recognition in the art as a separate subject of inventive effort. In fact, both groups are included in exactly the same class and thus a complete search would include claims of both groups. Applicants believe there would be a great economy of cost and effort on the part of the Office, and certainly to the applicants, if the closely related subject matter of both Group 1 and Group 4 were examined together at this time.

Further, Group 1 and Group 4 define subject matter so related and so dependent, that good judgment dictates their inclusion in one application. *Ex parte Sajatovich*, 100 USPQ 281, 284 (Bd. of Appeals 1952). Claims 1-17 and 24 of Group 1 recite a chimeric polypeptide. Group 4 (claims 18-23) also claims a chimeric polypeptide that includes a third heterologous domain. Applicants maintain that merely adding a third heterologous domain cannot be considered patentably distinct as asserted by the Office. The Board of Appeals in *Ex part Musselman*, 94 USPQ 212 (1952) reviewed this very issue and concluded that:

> "Since both groups of claims involve as their single principal distinguishing feature the concept of producing the starting compounds..., the two groups of claims are so closely related in substance as well as subject matter as to render the propriety of the requirement for division doubtful."

In the instant case, the claims of both Group 1 and Group 4 recite the same chimeric polypeptide. The chimeric polypeptide of claims 18-23 merely adds a third heterologous domain and there is no indication that a patentably distinct product occurs with this addition such that a basis is formed for two separate and distinct inventions. Applicants request that the Office withdraw the restriction requirement between Groups 1 and 4 and redesignate claims 1-24 as a single group.

The interdependence of the chimeric polypeptide (Groups 1-4) and the method of use thereof (Groups 7, 9, 11 and 12) is confirmed --indeed, it is mandated-- by virtue of the fact that the

description requirements of 35 U.S.C. §112 compel disclosure of different aspects of the invention in the one application which applicants have filed.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. *In re Kuehl,* 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Office held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.,* 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to

uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest, the Office is not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In view of the foregoing discussion, reconsideration for the withdrawal of the requirement for restriction is courteously requested.

In accordance with Office guidelines recited in MPEP Section 821.04, elected product claims (Group 1-4) found to recite patentable subject matter may be rejoined with the provisionally withdrawn method of use claims (Groups 7, 9, 11 and 12) and examined in this one application provided the method of use claims recite products corresponding to those found to be patentable during examination of the elected invention. In the event product claims 1-24 are found to recite patentable subject matter, non-elected claims 34-72 should be taken up for examination.

ELECTION OF SPECIES PURSUANT TO 35 U.S.C. 121

In response to the requirement for election of species, the applicants elect the following species:

(1) In Group 1, applicants elect with traverse the species HIV. The elected species reads on generic claims 1, 46 and 57 and species product claims 2-24 and method claims 34-45, 47-56 and 58-72. It is to be understood that this election is made with the proviso that (a) the requirement will be withdrawn upon the finding of an allowable generic claim; and (b) any non-elected species readable on an allowed generic claim will also be found allowable.

(2) In Group 11, applicants elect with traverse the species peptide. The elected species reads on generic claims 46 and 57 and species claims 47-56 and 58-72. It is to be understood that this election is made with the proviso that (a) the requirement will be withdrawn upon the finding of an allowable generic claim; and (b) any non-elected species readable on an allowed generic claim will also be found allowable.

Respectfully submitted,

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